

EXHIBIT 240

NOTICE OF PROPOSED LIMITATION OF THE CLIA CERTIFICATION AND SUSPENSIONS OF MEDICARE PAYMENTS WHEN A LABORATORY HAS FAILED TO PARTICIPATE SUCCESSFULLY IN A PROFICIENCY TESTING PROGRAM

(Date)

CLIA Director Name

Name of Laboratory

Address

City, State, ZIP Code

Dear (Laboratory Director):

RE: CLIA Number (CLIA Number)

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Public Law 100-578), it must satisfy all applicable requirements contained in §353 of the Public Health Service Act and be in compliance with the Conditions contained in Title 42, of the Code of Federal Regulations (CFR), Part 493.

During the (**first, second, third**) testing event of (**year**), (**laboratory's name**) performed proficiency testing for (**analyte, subspecialty, specialty**) and reported its results to (**PT program name**). This testing event was graded as being unsatisfactory. Our records also indicate that your laboratory was also unsatisfactory in the (**indicate previous failed event**) making the (**laboratory's name**) performance unsuccessful. After a careful review of these facts, I have determined that (**laboratory's name**) is not in compliance with the following CLIA Condition: 42 CFR 498.803 Successful Participation (**List PT Condition(s) related to each affected specialty**).

In accordance with 42 CFR 493.803(b), I am proposing to limit your certificate in (**analyte, subspecialty, or specialty**) to be effective 60 days from receipt of this notice or following the administrative hearing decision, if CMS prevails in this decision. Effective (date), I will suspend your approval to receive Medicare payment for testing in (**analyte, subspecialty, or specialty**) pursuant to 42 CFR 493.1826. Under a limitation of your CLIA certificate, you would be prohibited to test in (**analyte, subspecialty, or specialty**). The Medicaid State agency will also be notified of this action.

Your laboratory may request reinstatement of its certification under CLIA for (**analyte, subspecialty, or specialty**) when two consecutive proficiency testing events are successfully completed and a minimum of six months has passed as required by 42 CFR 493.807(a) and (b).

(Name)

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(Date)

If you believe that the results of the proficiency testing events are not correct, you may submit written or other evidence for my review no later than **(date)**. If I determine that this action is not warranted, the decision to limit your certification will be rescinded.

If you do not submit a response, or if after review of your response I determine that limitation of the certificate and suspension of your approval to receive Medicare payment are warranted, I will arrange to publish a routine notice in the newspaper to advise the public of these actions. I also reserve the right to notify physicians, providers, suppliers and other clients doing business with **(laboratory's name)**. In addition, your laboratory will be listed in the laboratory registry that is published annually by CMS and made available to physicians and the general public as a laboratory whose CLIA certificate has been limited, suspended, or revoked.

If you believe this determination is not correct, you may request a hearing before an administrative law judge of the Department of Health and Human Services, Departmental Appeals Board. Procedures governing this process are 42 CFR 493.1844 and 498.40 et seq. A written request for a hearing must be filed no later than 60 days from the date of receipt of this letter. For expedited handling, such a request may be made to the Associate Regional Administrator, Division of Health Standards and Quality, (complete mailing address of RO). At your option, you may instead submit a hearing request directly to:

Departmental Appeals Board
Civil Remedies Division
Attention: Room 637-D
HHH Building
200 Independence Avenue, S.W.,
Washington, DC 20201

and send a copy of your request to this office.

A request for a hearing should identify the specific issues and findings of fact and conclusions of law with which you disagree. It should also specify the basis for contending that the findings and conclusions are incorrect. You may be represented by counsel at a hearing at your own expense.

If your laboratory requests a hearing, it will retain its original CLIA certification until a decision is rendered by the administrative law judge.

(Name)

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(Date)

If you have any questions regarding this matter, please contact me at (**phone number**).

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Enclosure

cc: State Agency